REMARKS/ARGUMENTS

Claims 10-30 are active. Independent claim 10 has been amended to require the presence of Norovirus or Sapovirus specimen. Support for this limitation is found at least in the paragraph bridging pages 4-5 of the specification. Claims 10, 14 and 15 have been amended for clarity and to more particularly describe the sandwich assay reagents described on pages 8-10 of the specification. Support for these claims is also found in the section bridging pages 3-4 of the specification. Claim 22 has been amended to correct a typographical error. New claims 24-30 find descriptive support on pages 5-7 of the specification as follows: claim 24 (page 5, lines 11-12), claim 25 (page 6, 5th line from page bottom), claim 26 (page 5, lines 19-20), claim 27 (page 6, lines 1-13), claim 28 (page 6, lines 20-21), claim 29 (page 6, lines 17-18) and claim 30 (page 7, lines 1 and 5). No new matter has been added. Favorable consideration of this amendment and allowance of this case are respectfully requested.

Rejections—35 U.S.C. §112, first and second paragraphs

Claim 22 was rejected under 35 U.S.C. 112, first and second paragraph, as being indefinite and as lacking adequate descriptive support. These rejections are moot in view of the amendment above.

Rejection—35 U.S.C. §112, second paragraph

Claims 20 and 22 were rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps. These rejections are moot in view of the amendments above. Methods for detecting binding between a specimen and an immobilized antibody are well-known in the art and are disclosed and exemplified in the specification. Accordingly, the recited binding steps, though broader than steps directed to specific assays, are not

indefinite as they would be clearly understood by one of skill in the art in possession of the specification.

Rejection—35 U.S.C. 102

Claims 10-14, 20 and 21 were rejected under 35 U.S.C. 102(b) as being anticipated by Hardy, et al., Virol. 217:252. This rejection is moot in view of the amendments above. While Hardy's antibody carbonate-bicarbonate coating buffer (page 253, 2nd col. "Detection of Norwalk virus antigen in stools") has a pH of 9.6, it does not contain a Norovirus or Sapovirus specimen. As described in this section, the high pH coating buffer is removed after an overnight incubation by subsequent blocking and washing steps prior to application of a virus specimen. Accordingly, this rejection may now be withdrawn.

Rejection—35 U.S.C. 102

Claims 10, 13, 14, 16, 20 and 21 were rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi, et al., J. Med. Virol. 62:233 or Hale, et al., Clin. Diagnos. Virol. 5:27. This rejection is moot in view of the amendments above. Like Hardy, addressed above, Kobayashi (page 234, 2nd col., "ELISA for Detection of CV Antigen") and Hale (page 29, 1st col., section 2.2) both describe high pH antibody coating buffers which are subsequently removed prior to contact of an immobilized antibody with a virus specimen. Thus, these grounds of rejections may also be withdrawn.

Rejection—35 U.S.C. 103

Claims 10, 13, 15, 16, 20 and 21 were rejected under 35 U.S.C. 103(a) as being anticipated by Kobayashi, et al., J. Med. Virol. 62:233, in view of or Kitamoto, et al., J. Clin. Micro. 40:2459. This rejection is also moot in view of the amendments above since neither

Kobayashi nor Kitamoto suggest a composition having a pH ranging from 9.0 to 10.0 containing anti-virus antibodies as well as virus specimens. Kobayashi has been discussed above. Kitamoto was relied upon for disclosing Sapovirus antibodies SV68 and SV137, but does not disclose the high pH virus-specimen containing compositions of the invention.

Rejection—35 U.S.C. 103

Claims 10-15, 20 and 21 were rejected under 35 U.S.C. 103(a) as being anticipated by Hardy, et al., Virol. 217:252, in view of or Kitamoto, et al., J. Clin. Micro. 40:2459. This rejection cannot be maintained since Hardy and Kitamoto, as shown above, do not disclose the high pH virus-specimen containing compositions of the invention. Moreover, Hardy processes stool samples in PBS prior to performing the antigen capture assay (page 253, 2nd col. "Detection of Norwalk virus antigen in stools", first paragraph). It does not suggest or provide a reasonable expectation of success for the superior antigenic sensitivity obtained by specimen preparation at a higher pH as disclosed in the paragraph bridging pages 4-5 of the specification. Accordingly, this rejection cannot be sustained.

Conclusion

In view of the amendments and remarks above, the Applicants respectfully submit that this application is now in condition for allowance. An early notice to that effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon

Thomas M. Cunningham, Ph.D.
Registration No. 45,394

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/07)